

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Samuel Achilefu, Raghavan Rajagopalan,
Richard B. Dorshow, Joseph E. Bugaj

Title: Tissue-Specific Exogenous Optical Agents

Atty. Docket: MRD / 54DV

22388 U.S. PTO
10/814404

033104

CERTIFICATE OF MAILING BY EXPRESS MAIL - 37 CFR 1.10

'Express Mail' mailing label number: EV425512960US
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I certify that this paper or fee (along with the enclosures noted herein) is being deposited with the United States Postal Service 'Express Mail Post Office to Addressee' service under 37 CFR 1.10 on the above date and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Kenneth Eads
By: Kenneth Eads (person mailing paper)

UTILITY PATENT APPLICATION TRANSMITTAL

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is a request for filing, under 37 CFR § 1.53(b), a(n):

- ☐ Original (non-provisional) application.
- ☒ Divisional of prior application Serial No. 09/688,949, filed on October 16, 2000.
- ☐ Continuation of prior application Serial No. , filed on .
- ☐ Continuation-in-part of prior application Serial No. , filed on .

For Divisional and Continuation applications ONLY:

- ☒ Copy of Executed Declaration, Power of Attorney and Petition Form from parent application is enclosed (as noted below in Enclosures).
- ☒ Incorporation by Reference: The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied herewith, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

For all Divisional, Continuation and Continuation-in-part applications:

- ☐ Small Entity Status was requested in the prior application, and small entity status is still proper and desired.
- ☒ This application is assigned to MALLINCKRODT INC. of 675 McDonnell Boulevard, St. Louis, Missouri 63134 by virtue of an earlier assignment filed in the prior application at Reel 011251, Frame 0251.

PRELIMINARY AMENDMENT/CALCULATION OF FEES

- ☐ Please cancel claims without prejudice, and prior to calculating the fees. total claim(s), of which is(are) independent, is(are) pending after the amendment.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/688,949

10/16/2000

Samuel Achilefu

MRD / 54

9967

7590

08/08/2002

David E. Jefferies
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
441 Vine Street
Cincinnati, OH 45202-2917

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/688,949

Examiner

D. L. Jones

Applicant(s)

ACHILEFU ET AL.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/01; 3/30/01; 7/3/01; and 7/12/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 6 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 5 and 7-9 is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 10 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2&3
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 2, filed 1/23/01, wherein the specification and claims 1-6 were amended.

Note: Claims 1-14 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed indole compositions as set forth in independent claim 1 and uses thereof.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group I (claims 1-14) with traverse in Paper No. 6, filed 7/12/02, is acknowledged. The traversal is on the grounds that the restriction is improper since all the claims are directed to the structure designated as formula 1. Furthermore, Applicant goes on assert that unity of invention exists in the instant application and that all the compounds have the same utility. This is found non-persuasive because as set forth in the restriction requirement, the inventions depending on the variable values classify differently; thus, there is no common core. Also, species of one group neither anticipate nor render obvious species of another group. Thus, the inventions are separate and distinct and require a different search. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

Notes: (1) Applicant elected Group I (claims 1-14) directed to compounds/compositions and uses thereof comprising a 5-membered ring containing

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one nitrogen and one sulfur atom wherein W1 = sulfur; R3 - R7 = hydrogen; and Y1 = hydrogen. (2) The search was not extended beyond Applicant's elected species because prior art was found which could be used to reject the claims.

WITHDRAWN CLAIMS

4. Claims 3 and 6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 as written is ambiguous because it is unclear what 'physiological function monitoring' Applicant intends to be encompassed in the instant invention. Applicant is respectfully requested to clarify such terminology and point to page and line numbers for such support.

103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1616

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mifune et al (US Patent No. 5,780,218).

Mifune et al disclose a compound (column 3, Compound 13) that renders obvious Applicant's elected species. The species of Mifune et al renders obvious Applicant's elected species when R3 – R7 = hydrogen; W1 = sulfur; and Y1 = C1 alkyl (methyl) because it would be obvious to one of ordinary skill in the art to substitute a hydrogen for a methyl on a known compound since it is well established that the replacement of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results (In re Woods, 582 F.2d 638, 199 USPQ 137 (CCPA 1978)).

CLAIM OBJECTIONS

9. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 11-14 are allowable over the prior art of record because the prior art neither anticipates nor renders obvious a method of performing a diagnostic or therapeutic procedure wherein a mammal is administered an effective amount of an

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indole composition wherein W1 = sulfur; R3 – R7 = hydrogen; and Y1 = hydrogen. The search was not extended beyond the elected species.


ALLOWABLE CLAIMS

10. Claims 4, 5, and 7-9 are allowable over the prior art of record because the prior art neither anticipates nor renders obvious a method of performing a diagnostic or therapeutic procedure wherein a mammal is administered an effective amount of an indole composition wherein W1 = sulfur; R3 – R7 = hydrogen; and Y1 = hydrogen. The search was not extended beyond the elected species.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

August 5, 2002

SUBSTITUTE FORM PTO-1449
(MODIFIED)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
MRD/54

Sheet 1 (A) of 1

SERIAL NO.
09/688,94

JUL 03 2001
PATENT & TRADEMARK OFFICE

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT
Samuel Achilefu, et al.

FILING DATE
October 16, 2000

GROUP
2877

(37 CFR 1.58(a))

(Use several sheets if necessary)

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	
	A.A						
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FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	A.L					
	A.M					
	A.N					
	A.O					
	A.P					
	A.Q					

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

707	A.R	L. Hansen et al., <u>Synthesis of the Sulphonate and Phosphonate Derivatives of Mercaptoacetyltryglycine, X-Ray Crystal Structure of Na₂(ReO/Mercaptoacetyltryglycyl-Aminomethanesulphonate)·3H₂O</u> , Metal-Based Drugs, Vol. 1, No. 1, 1993, 31-39.
707	A.S	G. Muller et al.(ed.), <u>Medical Optical Tomography, Functional Imaging and Monitoring</u> , SPIE Optical Engineering Press, The International Society of Optical Engineering, Bellingham, WA, 1993.
707	A.T	P.L. Southwick et al., <u>"One Pot" Fischer Synthesis of (2, 3, 3-Trimethyl-3-H-Indol-5-yl)-Acetic Acid Derivatives as Intermediates for Fluorescent Biolabels</u> , Org. Prep. Proced. Int. Briefs, Vol. 20, No. 3, 1988, 279-284.

EXAMINER

DATE CONSIDERED

TD Jones

8/5/02

EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered. Include a copy of this form with next communication to applicant.

SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
MRD/54SERIAL NO.
09/688,948INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(37 CFR 1.99(b))

(Use several sheets if necessary)

APPLICANT
Samuel Achilefu, et al.FILING DATE
October 16, 2000GROUP
2877

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT & TRADEMARK OFFICE	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE APPROPRIATE
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	A.P					
	A.Q					

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

A.R	Christopher C. Baker, M.D., <u>Epidemiology of Trauma Deaths</u> , Amer. Jour. of Surg., Vol. 140, 1980, pp. 144-150.
A.S	John Baldas et al., <u>Preparation, HPLC Studies and Biological Behaviour of ^{90m}Tc- and ^{99m}TcN-radiopharmaceuticals Based on Quinoline Type Ligands</u> , Nucl. Med. Biol., Vol. 19, No. 4, 1992, pp. 491-496.
A.T	Frank B. Corra, M.D., <u>Multiple Organ Failure Syndrome</u> , New Horizons: Multiple Organ Failure, Society of Critical Care Medicine, 1989, pp. 1-24.

EXAMINER

DATE CONSIDERED

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SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
MRD/54SERIAL NO.
09/688,548INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98(b))

APPLICANT
Samuel Achilefu, et al.FILING DATE
October 16, 2000GROUP
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U.S. PATENT DOCUMENTS

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FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

B.R	Peter L. Choyke et al., <u>Hydrated clearance of gadolinium-DTPA as a measurement of glomerular filtration rate</u> , Kidney International, Vol. 41, 1992, pp. 1595-1598.
B.S	Cdr. P.D. Doolan, MC, USN et al., <u>A Clinical Appraisal of the Plasma Concentration and Endogenous Clearance of Creatinine</u> , Amer. Jour. of Med., Vol. 32, 1962, pp. 65-79.
B.T	Richard B. Dorshow et al., <u>Monitoring physiological function by detection of exogenous fluorescent contrast agents</u> , Optical Diagnostics of Biological Fluids IV, A. Priezzhev and T. Asakura, Eds., Proceedings of SPIE 1999, Vol. 3599, pp. 2-8.

EXAMINER

DATE CONSIDERED

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SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
MRD/54SERIAL NO.
09/688,945INFORMATION DISCLOSURE
BY INVENTOR/APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98(b))

APPLICANT
Samuel Achilefu, et al.FILING DATE
October 16, 2000GROUP
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	PLING/PATE APPROPRIA
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	C.Q					

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

C.R	Richard B. Dorshow et al., <u>Noninvasive Fluorescence Detection of Hepatic and Renal Function</u> , Journal of Biomedical Optics, Vol. 3, No. 3, 1998, pp. 340-345.
C.S	James H. Flanagan, Jr. et al., <u>Near-Infrared Heavy-Atom-Modified Fluorescent Dyes for Base-Calling in DNA-Sequencing Applications Using Temporal Discrimination</u> , Anal. Chem., Vol. 70, No. 13, 1998, pp. 2676-2684.
C.T	P. Guesry et al., <u>Measurement of glomerular filtration rate by fluorescent excitation of non-radioactive meglumine iohalamate</u> , Clinical Nephrology, Vol. 3, No. 4, 1975, pp. 134-138.

EXAMINER

DATE CONSIDERED

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SUBSTITUTE FORM PTO-1449
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Samuel Achilefu, et al.FILING DATE
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(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

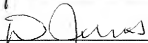
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OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

D.R	John Bernard Henry, M.D., <u>Clinical Diagnosis and Management by Laboratory Methods</u> . W.B. Saunders Company, 17th Ed., 1984, pp. vii-1502.
D.S	Richard Lewis et al., <u>Comparative Evaluation of Urographic Contrast Media, Inulin, and ^{99m}Tc-DTPA Clearance Methods for Determination of Glomerular Filtration Rate in Clinical Transplantation</u> , Transplantation, Vol. 48, No. 5, 1989, pp. 790-796.
D.T	S. Lundqvist et al., <u>Iohexol Clearance for Renal Function Measurement in Gynecologic Cancer Patients</u> , Acta Radiologica, Vol. 37, 1996, pp. 582-586.

EXAMINER 	DATE CONSIDERED 8/5/02
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

E.R.	Roland Muller-Suur et al., <u>Glomerular Filtration and Tubular Secretion of MAG-3 in the Rat Kidney</u> , The Journal of Nuclear Medicine, Vol. 30, 1989, pp. 1986-1991.
E.S.	Dennis L. Nicoso et al., <u>Chemistry of technetium radiopharmaceuticals 1: Chemistry behind the development of technetium-99m compounds to determine kidney function</u> , Coordination Chemistry Reviews, Vol. 184, 1999, pp. 91-123.
E.T.	Carlos A. Rabito et al., <u>Renal Function in Patients at Risk of Contrast Material-Induced Acute Renal Failure: Noninvasive, Real-Time Monitoring</u> , Radiology, Vol. 186, No. 3, 1993, pp. 851-854.

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APPLICANT
Samuel Achilefu, et al.FILING DATE
October 16, 2000GROUP
2877

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

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FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	F.R	G. Regel, M.D. et al., <u>Treatment Results of Patients with Multiple Trauma: An Analysis of 3406 Cases Treated between 1972 and 1991 at a German Level 1 Trauma Center</u> , The Journal of Trauma, Vol. 38, No. 1, 1995, pp. 70-77.
	F.S	G.A. Reynolds et al., <u>Stable Heptamethine Pyrylium Dyes That Absorb in the Infrared</u> , J. Org. Chem., Vol. 42, No. 5, 1977, pp. 885-888.
	F.T	Francoise Roch-Rameil et al., <u>Renal excretion and tubular transport of organic anions and cations</u> , Oxford University Press, N.Y., Handbook of Physiology, Sec. 8, Neurological Physiology, Vol. II, E.E. Windhager, Ed., 1992, pp. 2189-2262.

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SUBSTITUTE FORM PTO-1449
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PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
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09/688,944INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT
Samuel Achilefu, et al.FILING DATE
October 16, 2000GROUP
28771

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	G.A						
	G.B						
	G.C						
	G.D						
	G.E						
	G.F						
	G.G						
	G.H						
	G.I						
	G.J						
	G.K						

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	G.L					
	G.M					
	G.N					
	G.O					
	G.P					
	G.Q					

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	G.R	Morgan Sohtell et al., <u>FITC-inulin as a kidney tubule marker in the rat</u> , Acta Physiol Scand, Vol. 119, 1983, pp. 313-316.
	G.S	Carl E. Spelcher, M.D., <u>The Right Test, A Physician's Guide to Laboratory Medicine</u> , W.B. Saunders Company, Harcourt, Brace, Jovanovich, Inc., 1990, pp v - 174.
	G.T	W. Newton Tauxe, <u>Tubular Function</u> , Nuclear Medicine in Clinical Urology and Nephrology, Appleton-Century-Crofts, Prentice-Hall, Inc., 1985, pp. 77-105.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered. Include a copy of this form with next communication to applicant.

RECEIVED
APR 05 2002
TECH CENTER 1600 PDR

SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
MRD/54SERIAL NO.
09/686,941INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use separate sheets if necessary)

APPLICANT
Samuel Achilefu, et al.FILING DATE
October 16, 2000GROUP
287761

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	H.A					
	H.B					
	H.C					
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	H.J					
	H.K					

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H.L					
H.M					
H.N					
H.O					
H.P					
H.Q					

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

H.R	Nicholas L. Tilney, M.D., <u>Acute Renal Failure in Surgical Patients, Causes, Clinical Patterns, and Care</u> , Surgical Clinics of North America, Vol. 63, No. 2, 1983, pp. 357-377.
H.S	Michael F. Tweedle, Ph.D. et al., <u>A Noninvasive Method for Monitoring Renal Status at Bedside</u> , Investigative Radiology, Vol. 32, No. 12, 1997, pp. 802-805.
H.T	Bruce E. VanZee, M.D. et al., <u>Renal Injury Associated with Intravenous Pyelography in Nondiabetic and Diabetic Patients</u> , Annals of Internal Medicine, Vol. 89, 1978, pp. 51-54.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered. Include a copy of this form with next communication to applicant.

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APR 05 2001
TECH CENTER 1600

Notice of References Cited

Application/Control No.

09/688,949

Applicant(s)/Patent Under
Reexamination
ACHILEFU ET AL.

Examiner

D. L. Jones

Art Unit

1816

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,780,218	07-1998	Mifune et al	430/599
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,949	10/16/2000	Samuel Achillefu	MRD / 54	9967

7590 01/29/2003
David E. Jefferies
Wood, Herron & Evans, L.L.P.
2700 Carew Tower
441 Vine Street
Cincinnati, OH 45202-2917

EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
2003 FEB -3 PM 3:12
WOOD, HERRON & EVANS

Office Action Summary

Application No.

09/688,949

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(c).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-14 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7-11, 13, and 14 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/11/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 8, filed 11/11/022, wherein claim 1 was amended and claim 3 was canceled.

Note: Claims 1, 2, and 4-14 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENTS

2. Applicant's arguments with respect to claims 1, 2, and 10 have been considered but are moot in view of the new ground(s) of rejection.

Note: It is duly noted that Applicant is requesting that even if the elected species (composition) is found, the search of the method claims should continue beyond the elected species.

The request is denied. The compounds used in the method claims classify differently based on the variable definitions (this is true for the composition claims as well). Thus, the method claims will be examined like the composition claims, especially since the restriction requirement includes both the composition and the method claims in the groups.

WITHDRAWN CLAIMS

3. Claims 3 and 6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

NEW GROUNDS OF REJECTION

102 Rejection

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 5, 7-11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Durmaz et al (Arzneimittel-Forschung (1998), Vol. 48, No. 12, pp. 1179-1184).

Durmaz et al disclose the effects of benzimidazole, imidazole, and benzothiazole derivatives on liver and renal functions. The compounds were administered to Wistar rats orally, intramuscularly, or intravenously and blood samples taken as designated intervals. In particular, Durmaz et al disclose the compound 3-ethyl benzothiazolium and uses thereof which is encompassed in Applicant's invention when W1 = sulfur; R3-R7 = hydrogen; and Y1 is alkyl (see entire document, especially, abstract; pages 1180-1181, 'Materials and methods'; page 1180, Figure 1, Compound 3; page 1181; 'In vivo effects of the compounds' and 'Effects of compound 3 on the biochemical parameters').

Note: It should not be construed that the search has been extended over the full scope of the claims because of the above 102 rejection of a species that is not Applicant's elected species. While searching for Applicant's elected species, the above species was found. Thus, only Applicant's elected species and the species wherein W1 = sulfur; R3-R7 = hydrogen; and Y1 = alkyl have been examined.

103 Rejection

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 4, 5, 7-11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durmaz et al (Arzneimittel-Forschung (1998), Vol. 48, No. 12, pp. 1179-1184).

Durmaz et al disclose the effects of benzimidazole, imidazole, and benzothiazole derivatives on liver and renal functions. The compounds were administered to Wistar rats orally, intramuscularly, or intravenously and blood samples taken as designated intervals. In particular, Durmaz et al disclose the compound 3- ethyl-benzothiazolium complex that is encompassed in Applicant's invention when W1 = sulfur; Y1 = ethyl; and R3-R7 = hydrogen. Hence, while Durmaz et al disclose a 3-ethyl-benzothiazolium complex, the reference fails to disclose a benzothiazolium complex wherein Applicant's variables R3 –R7 and Y1 are all hydrogen (see entire document, especially, abstract; pages 1180-1181, 'Materials and methods'; page 1180, Figure 1, Compound 3; page 1181; 'In vivo effects of the compounds' and 'Effects of compound 3 on the biochemical parameters').

It would be have been obvious to one of ordinary skill in the art at the time the invention was made that the species of Durmaz et al renders obvious Applicant's

elected species (R3-R7 = hydrogen; W1 = sulfur; and Y1 = hydrogen) because the skilled practitioner would recognize that the substitution of a hydrogen for a lower alkyl on a known compound is within the skill of an practitioner in the art. Furthermore, the artisan would recognize that the replacement of hydrogen for a lower alkyl on a known compound is not a patentable modification absent unexpected or unobvious results.

CLAIM OBJECTIONS

8. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: Claim 12 is distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a method of cardiac function monitoring comprising administer a compound as set forth in independent claim 4 wherein W1 = sulfur; R3-R7 = hydrogen; and Y1 = hydrogen.


COMMENTS/NOTES

9. It should be noted that the rejection over Mifune et al (US Patent No. 5,780,218) was withdrawn because Applicant amended the claim to incorporate that the composition is a pharmaceutical. Hence, the term 'pharmaceutical' as used in the preamble requires that the composition be capable of use as a pharmaceutical.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

January 23, 2003

Notice of References Cited

Application/Control No.

09/688,949

Applicant(s)/Patent Under
Reexamination
ACHILEFU ET AL.

Examiner

D. L. Jones

Art Unit

1616

Page 1 of 1

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	K	US-			
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	M	US-			

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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Durmaz et al (1998), Arzneimittel-Forschung, Vol. 48, No. 12, pp. 1179-1184.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.06(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.